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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/853,918	05/10/2001	Stanley R. Krystek	DB24NP/30436.46USU1	7606

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EXAMINER

PAK, YONG D

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 07/30/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

09/853,918

Applicant(s)

KRYSTEK ET AL.

Examiner

Yong Pak

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— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-56 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-56 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The preliminary amendment filed on October 5, 2001, amending the specification, has been entered.

Claims 1-30 are pending.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-17, 32, 53 and 55-56, drawn to a modified IMPDH (inosine 5'-monophosphate dehydrogenase) polypeptide, classified in class 435, subclass 190.
- II. Claims 18-21, drawn to a protein multimer, classified in class 530, subclass 350.
- III. Claim 22-31 and 54, drawn to DNA encoding the modified IMPDH polypeptide of Invention I, vector comprising the DNA, host cell comprising the vector and a method of producing the polypeptide, classified in class 435, subclass 190.
- IV. Claims 33-35, drawn to an antibody against the polypeptide of Invention I, classified in class 530, subclass 387.9.
- V. Claims 36-41, drawn to a method of identifying an agent that inhibits the multimer of Invention II, classified in class 514, subclass 789.

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- VI. Claim 42-52, drawn to a method for improving resolution of an X-ray crystal structure of a IMPDH polypeptide, classified in class 378, subclass 73.

In addition to election one of the patentably distinct inventions of I-VI, applicants are required to further elect ONE IMPDH sequence (along with its corresponding characteristics, whether the sequence is a type I or type II IMPDH, location of the oligopeptide domain and whether the sequence comprises a tri-peptide or tetra-peptide and its corresponding amino acid sequence, etc.) or ONE DNA sequence encoding the IMPDH. The disclosure contains many modified IMPDH with different structure and different function.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-IV are patentably distinct because a protein, a multimer, DNA, and an antibody are different compounds, each with its own chemical structure and function, and they have different utilities. DNA of Inventions III are patentably distinct as encoding enzymes with different structures, functions, substrate specificities, and utilities. The proteins of Inventions I are patentably distinct as having different structures, functions, substrate specificities, and utilities.

The DNA molecule of invention III is not limited in use to the production of polypeptide of invention I, respectively, and can be used as a hybridization probe, and protein of Invention I can be obtained by a materially different method such as by biochemical purification. The structure of an antibody of Invention IV is not predictable

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from the structure of the protein of Invention I and an antibody can cross-react with various proteins. The protein of Invention I and the multimer of Invention II are patentably distinct because the two products have different function, substrate specificity, physical and chemical characteristics.

Inventions I and (V and VI) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the protein of Invention I can be used for the production of the antibody of Invention III.

The methods of Inventions V-VI are patentably because the methods have different effects and utilities.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 703-308-9363. The examiner can normally be reached on 8:00 A.M. to 4:30 P.M weekdays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Yong Pak
Patent Examiner

July 26, 2002


PONNATHAPU ACHUTAMURTHY
SUPERVISORY PATENT EXAMINER
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